



[Billing Code 6335-01]

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2012-0040]

16 CFR Part 1199

Children's Toys and Child Care Articles Containing Phthalates; Proposed

Guidance on Inaccessible Component Parts

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed Guidance.

SUMMARY: On August 14, 2008, Congress enacted the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314. Section 108 of the CPSIA, as amended by Public Law 112-28, provides that the prohibition on specified products containing phthalates does not apply to any component part of children's toys or child care articles that is not accessible to a child through normal and reasonably foreseeable use and abuse of such product. In this document, the Consumer Product Safety Commission (CPSC or Commission) proposes guidance on inaccessible component parts in children's toys or child care articles subject to section 108 of the CPSIA.

DATES: Written comments and submissions in response to this notice must be received by **[insert date that is 60 days after publication]**

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2012-0040, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through www.regulations.gov.

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this proposed guidance. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7254; khatlelid@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

1. Prohibition on Certain Phthalates

On August 14, 2008, Congress enacted the CPSIA (Pub. L. 110-314), as amended on August 12, 2011, by Pub. L. 112-28. Section 108 of the CPSIA, titled “Prohibition on

Sale of Certain Products Containing Specified Phthalates,” permanently prohibits the sale of any “children's toy or child care article” containing more than 0.1 percent of three specified phthalates (di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP)). Section 108 of the CPSIA also prohibits, on an interim basis, “toys that can be placed in a child's mouth” or “child care article” containing more than 0.1 percent of three additional phthalates (diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP)). These prohibitions became effective on February 10, 2009. 15 U.S.C. 2057c(a), (b). The terms or phrases “children’s toy,” “toy that can be placed in a child’s mouth,” and “child care article,” are defined in section 108(g) of the CPSIA. A “children's toy” is defined as a “consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays.” A toy can be placed in a child’s mouth “if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the children’s product can only be licked, it is not regarded as able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in a child’s mouth.” The term “child care article” means “a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething.” 15 U.S.C. 2057c(g).

Section 108 of the CPSIA also directed the Commission, not earlier than 180 days after the date of enactment of this Act [enacted Aug. 14, 2008], to appoint a Chronic Hazard Advisory Panel (CHAP), pursuant to the procedures of section 28 of the CPSA (15 U.S.C. 2077), to study the effects on children’s health of all phthalates and phthalate

alternatives as used in children's toys and child care articles. 15 U.S.C. 2057c(b)(2). The Commission appointed the CHAP on April 14, 2010, to study the effects on children's health of all phthalates and phthalate alternatives, as used in children's toys and child care articles. The CHAP currently is working on a report, including recommendations to the Commission.

2. Inaccessible Component Parts and the Phthalates Prohibition

Pub. L. 112-28 amended section 108(d) of the CPSIA to provide an exclusion for certain products containing inaccessible phthalates component parts. That section states:

The prohibitions . . . shall not apply to any component part of a children's toy or child care article that is not accessible to a child through normal and reasonably foreseeable use and abuse of such product, as determined by the Commission. A component part is not accessible under this paragraph if such component part is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product. Reasonably foreseeable use and abuse shall include swallowing, mouthing, breaking, or other children's activities, and the aging of the product.

15 U.S.C. 2057c(d)(1).

The Commission was directed within 1 year after the date of enactment of Pub. L. 112-28 [enacted August 12, 2011] to: (A) promulgate a rule providing guidance with respect to what product components, or classes of components, will be considered to be inaccessible; or (B) adopt the same guidance with respect to inaccessibility that was adopted by the Commission with regards to accessibility of lead under section 101(b)(2)(B) (15 U.S.C. 1278a(b)(2)(B)), with additional consideration, as appropriate, of whether such component can be placed in a child's mouth. 15 U.S.C. 2057c(d)(3).

The exclusion for inaccessible component parts for phthalates mirrors the language on inaccessible parts in the CPSIA with regard to the limits on lead content in children's

products. The interpretative rule on lead provided that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children's activities, and the aging of the product. 15 U.S.C. 1278a(b)(2). However, paint, coatings, or electroplating could not be considered to be a barrier that would render lead in the substrate to be inaccessible to a child. 15 U.S.C. 1278a(b)(3). Section 108 did not specifically disqualify paint, coatings, or electroplating as barriers that would render phthalates inaccessible. Because the Commission proposes to adopt the same guidance with respect to inaccessibility for phthalates that was adopted by the Commission with regard to inaccessibility of lead, the proposed guidance states that paint, coatings, and electroplating may not be considered a barrier that would render phthalate-containing component parts of toys and child care articles inaccessible. Moreover, in some applications, phthalates are added to paint, printing inks, or coatings. However, the Commission seeks comments, information, and data regarding whether certain paint, coatings, or electroplating could ever be considered a barrier in the context of phthalates, and whether such materials could result in sealed covering or casing that would not become physically exposed through reasonably foreseeable use and abuse of the product.

In addition, Pub. L. 112-28 also includes a provision for phthalates, which is not contained in the statutory requirements for assessing inaccessibility for lead in children's products. Under section 108(d)(2) of the CPSIA, the Commission may revoke any or all exclusions granted based on the inaccessible component parts provision of section 108 of the CPSIA, at any time, and require that any or all component parts manufactured after

such exclusion is revoked, comply with the prohibitions of phthalates, if the Commission finds, based on scientific evidence, that such compliance is necessary to protect the public health or safety. 15 U.S.C. 2057c(d)(2).

B. Proposed Guidance for Inaccessible Component Parts in Phthalates

The Commission's interpretive rule regarding inaccessible component parts with respect to lead content was published in the *Federal Register* on August 7, 2009 (74 FR 39535) and codified at 16 CFR 1500.87 (Children's products containing lead: inaccessible component parts). The Commission proposes to adopt the lead guidance with respect to inaccessibility for phthalates, with the exception of polyvinyl chloride (PVC or vinyl) or other plasticized materials covering mattresses and other sleep surfaces designed or intended by the manufacturer to facilitate sleep of children age 3 and younger.

Accordingly, this proposed guidance would adopt the same definitions and tests used in the interpretative rule regarding inaccessibility of lead-containing parts. An "accessible component part" is one that a child may touch, and an "inaccessible component part" is one that is located inside the product, and cannot be touched by a child, even if such a part is visible to a user of the product. An accessible component is defined as one where children may contact a lead-containing component part with their fingers or tongues. The tests to determine whether parts are accessible are identical to those already in use by the Commission for addressing sharp points and sharp metal or glass edges on toys or other articles intended for use by children. The Commission's regulations under 16 CFR 1500.48–1500.49 provide specific technical requirements for determining accessibility of sharp points or edges through the use of accessibility probes.

These sections provide that an accessible sharp point or edge is present in the product if the test indicates that any part of the specified portion of the accessibility probe contacts the sharp part. Thus, an “accessible component part” of a children’s product is defined as one that can be contacted by any part of the specified portion of the accessibility probe. The regulations at 16 CFR1500.48–49 provide that a test for accessibility of sharp points or edges shall be applied before and after use and abuse tests, referencing 16 CFR 1500.50 through 1500.53 (excluding the bite test—paragraph (c) of 16 CFR 1500.51–1500.53).

Use and abuse testing may also be used to evaluate accessibility of phthalate-containing component parts of children’s toys and child care articles as a result of normal and reasonably foreseeable use and abuse of the product. The scope of the use and abuse testing regulations does not cover products for children over 96 months of age. However, a “children’s toy” is defined as a “consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays.” Therefore, the proposed guidance for the testing of products for determining accessibility based on the use and abuse tests will be extended to children older than 96 months of age and up through age 12 years. This proposed guidance provides that the testing indicated for products for children aged 37–96 months of age should also be used to evaluate the products for children up through age 12 years. Further, as children 12 years of age or younger grow and mature, they become, in many respects, indistinguishable from children older than 12 years, and even adults. Consequently, the intentional disassembly or destruction of products by children older than age 8 years, by means or knowledge not generally available to younger children, should not be

considered in evaluating products for accessibility of phthalate-containing components. For example, accessibility arising from the use of tools, such as a screwdriver, should not be considered in accessibility and use and abuse testing.

The interpretive rule on lead also specified that a lead-containing part of a children's product that is enclosed or covered by fabric is to be considered inaccessible to a child, unless the product, or part of the product, in one dimension, is smaller than 5 centimeters. This provision addressed the possibility that a fabric covering is not a suitable barrier to the potential transfer of lead from the part to a child, if the part can be placed in a child's mouth. As is the case with lead, a fabric covering may not be a suitable barrier to the potential transfer of phthalates from a product or component part to a child, if the part can be placed in a child's mouth. If the product can be mouthed, the chemical that is present could mix with saliva that soaks through the fabric and then be transferred back into a child's mouth during further mouthing activity. With the exception of certain vinyl (or other plasticized material) covered mattresses/sleep surfaces, as discussed further below, a children's toy or child care article that is, or contains, a phthalate-containing part that is enclosed, encased, or covered by fabric, and passes the appropriate use and abuse tests on such covers and parts, would be considered to be inaccessible to a child, unless the product or part of the product, in one dimension, is smaller than 5 centimeters. Such fabric-covered items (including dolls, or plush toys with internal plasticized structural parts or housing for electronic parts) should be evaluated for the integrity of the coverings, including seams, using the appropriate use and abuse tests at 16 CFR 1500.50 through 1500.53 (excluding the bite test—paragraph (c) of 16 CFR 1500.51–1500.53). In addition, because the material beneath a fabric

covering would be considered to be accessible to a child in the case that mouthing or swallowing of the part may occur, use and abuse testing should be used to evaluate the potential for small components to be removed from products, using the appropriate tests at 16 CFR 1500.50 through 1500.53 (excluding the bite test—paragraph (c) of 16 CFR 1500.51–1500.53).

Section 108(d)(3)(B) provides that if the Commission elects to adopt the same guidance with respect to inaccessibility that was adopted by the Commission with regard to accessibility of lead under section 101(b)(2)(B) of the CPSIA, the Commission must give “additional consideration, as appropriate, of whether such component can be placed in a child’s mouth.” 15 U.S.C. 2057c(d)(3). Accordingly, with respect to child care articles, the Commission reviewed phthalate-containing vinyl or other plasticized materials covering mattresses and sleep surfaces designed or intended by the manufacturer to facilitate sleep of children age 3 and younger that have removable fabric covers. These mattresses or sleep surfaces are too large to be placed in a child’s mouth. Although such mattresses or sleep surfaces may be covered by fabric, such as sheets or mattress pads, additional consideration was given to whether children would become physically exposed to the vinyl or other plasticized materials covering the surface through reasonably foreseeable use and abuse of the products, including swallowing, mouthing, breaking, or other children’s activities, and the aging of the product. 15 U.S.C. 2057c(d)(1). There may be instances in which a child’s skin comes into close contact with a fabric covering over a phthalate-containing item for large portions of a day, such as a vinyl or other plasticized material covering a mattress or other sleep surface. Young children typically spend more than half of each day sleeping or resting, likely on a

mattress or similar item.¹ While a mattress is typically covered with a sheet or mattress pad, such non-permanently affixed coverings, that are either supplied with the mattress or provided by the consumer, should not be considered to render the underlying material inaccessible. As with the potential transfer of phthalates by saliva during mouthing of an item, a mattress cover dampened with a spilled beverage, saliva, sweat, urine, or other liquid, could facilitate phthalate migration through the fabric. Furthermore, a nonpermanent covering cannot be assumed to be in use at all times; if it is not, the mattress could no longer be considered inaccessible. For these reasons, vinyl (or other plasticized material) covered mattresses/sleep surfaces, which contain phthalates, designed or intended by a manufacturer to facilitate sleep for children age 3 and younger, should not be considered to be made inaccessible through the use of a fabric covering.

The Commission appointed the CHAP on April 14, 2010, to study the effects on children's health of all phthalates and phthalate alternatives, as used in children's toys and child care articles. Currently, the CHAP is working on a report, including recommendations to the Commission. Accordingly, any guidance concerning phthalates may be modified and revised, as appropriate, based on the findings and recommendations of the CHAP.

C. Effective Date

The Commission was directed to provide guidance on phthalate-containing inaccessible component parts by August 12, 2012. Although guidance documents do not require a particular effective date under the Administrative Procedure Act, 5 U.S.C.

¹ U.S. EPA (Environmental Protection Agency). (2011) Exposure factors handbook: 2011 edition. National Center for Environmental Assessment, Washington, DC; EPA/600/R-09/052F. Available from the National Technical Information Service, Springfield, VA, and online at <http://www.epa.gov/ncea/efh>.

553(d)(2), the Commission recognizes the need for providing the guidance expeditiously. Accordingly, the proposed guidance would take effect upon publication of a final guidance in the *Federal Register*.

List of Subjects in 16 CFR Part 1199

Business and industry, Infants and children, Consumer protection, Imports, Toys

D. Conclusion

For the reasons stated above, the Commission proposes to add 16 CFR part 1199, as follows:

PART 1199- CHILDREN’S TOYS AND CHILD CARE ARTICLES CONTAINING PHTHALATES: GUIDANCE ON INACCESSIBLE COMPONENT PARTS

Authority: 15 U.S.C. 1251–1289, 86 Stat. 1207, 125 Stat. 273.

§ 1199 Children’s Toys and Child Care Articles: Phthalate-Containing Inaccessible Component Parts.

(a) Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) permanently prohibits the sale of any “children's toy or child care article” containing more than 0.1 percent of three specified phthalates (di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP)). Section 108 of the CPSIA also prohibits, on an interim basis, “toys that can be placed in a child's mouth” or “child care article” containing more than 0.1 percent of three additional phthalates (diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP)). A “children's toy” is defined as a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child

plays. A toy can be placed in a child's mouth if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the children's product can only be licked, it is not regarded as able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth. The term "child care article" means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething.

(b) Section 108 (d) of the CPSIA provides that the prohibitions in paragraph (a) do not apply to component parts of a children's toy or child care article that are not accessible to children through normal and reasonably foreseeable use and abuse of such product, as determined by the Commission. A component part is not accessible if it is not physically exposed, by reason of a sealed covering or casing, and does not become physically exposed through reasonably foreseeable use and abuse of the product, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product.

(c) Section 108(d)(3) of the CPSIA directs the Commission to promulgate, by August 12, 2012, a rule to provide guidance with respect to what product components or classes of components will be considered to be inaccessible for a children's toy or child care article that contains phthalates or adopt the same guidance with respect to inaccessibility that was adopted by the Commission with regards to accessibility of lead under section 101(b)(2)(B) (15 U.S.C. 1278a(b)(2)(B)), with additional consideration, as appropriate, of whether such component can be placed in a child's mouth. 15 U.S.C. 2057c(d)(3). The Commission adopts the same guidance with respect to inaccessibility

for the phthalates that was adopted by the Commission with regards to accessibility of lead.

(d) The accessibility probes specified for sharp points or edges under the Commission's regulations at 16 CFR 1500.48-1500.49 will be used to assess the accessibility of phthalate-containing component parts of a children's toy or child care article. A phthalate-containing component part would be considered accessible if it can be contacted by any portion of the specified segment of the accessibility probe. A phthalate-containing component part would be considered inaccessible if it cannot be contacted by any portion of the specified segment of the accessibility probe.

(e) For children's toys or child care articles intended for children that are 18 months of age or younger, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.51 (excluding the bite test of 1500.51(c)), will be used to evaluate accessibility of phthalate-containing component parts of a children's toy or child care article as a result of normal and reasonably foreseeable use and abuse of the product.

(f) For children's toys or child care articles intended for children that are over 18 months, but not over 36 months of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.52 (excluding the bite test of 1500.52(c)), will be used to evaluate accessibility of phthalate-containing component parts of a children's toy or child care article as a result of normal and reasonably foreseeable use and abuse of the product.

(g) For children's toys intended for children that are over 36 months, but not over 96 months of age, the use and abuse tests set forth under the Commission's regulations at 16

CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of 1500.53(c)), will be used to evaluate accessibility of phthalate-containing component parts of a children's toy as a result of normal and reasonably foreseeable use and abuse of the product.

(h) For children's toys intended for children over 96 months through 12 years of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of 1500.53(c)) intended for children aged 37–96 months will be used to evaluate accessibility of phthalate-containing component parts of a children's toy as a result of normal and reasonably foreseeable use and abuse of the product.

(i) Because the Commission proposes to adopt the same guidance with respect to inaccessibility for phthalates that was adopted by the Commission with regard to inaccessibility of lead, paint, coatings, and electroplating may not be considered a barrier that would render phthalate-containing component parts of toys and child care articles inaccessible. A children's toy or child care article that is or contains a phthalate-containing part that is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is considered inaccessible to a child, unless the product or part of the product, in one dimension, is smaller than 5 centimeters. However, vinyl (or other plasticized material) covered mattresses/sleep surfaces which contain phthalates that are designed or intended by the manufacturer to facilitate sleep of children age 3 and younger, are considered accessible and would not be considered inaccessible through the use of fabric coverings, including sheets and mattress pads.

(j) The intentional disassembly or destruction of products by children older than age 8 years, by means or knowledge not generally available to younger children,

including use of tools, will not be considered in evaluating products for accessibility of phthalate-containing components.

Dated: July 26, 2012

Todd A. Stevenson, Secretary
Consumer Product Safety Commission

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